REMARKS

Reconsideration and allowance of the present application is respectfully requested in view of the foregoing amendments and the following additional remarks which have addressed all the issues raised in the December 06, 2004, Office Action or otherwise have rendered them moot.

Claims 36 - 44 are under consideration in this application. Claims 45 – 66 stand withdrawn pursuant to Examiner's imposed restriction requirement. Claims 40 and 41 have been amended. The claim amendments are in order to more particularly define and distinctly claim applicant's invention and/or to better recite or describe the features of the present invention as claimed. No new matter is believed to be added.

In the Office Action, the Examiner rejected claims 40 and 41 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter of the invention.

Also, the Examiner rejected claims 36, 37, 40 and 41 under 35 U.S.C. § 102(b) as allegedly anticipated by Itay (U.S. 5, 053, 050), in light of Thomas (1997, Taber's Cyclopedic Medical Dictionary, 18th Ed.), and Boden (1999, Clin. Orthop. 376:S84-S94).

Further, the Examiner rejected claims 38 and 42 under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5, 053, 050), Thomas and Boden as applied to claims 36, 37, 40 and 41 above, and further in view of Johnson et al., (U.S. 4,156,296).

Also, the Examiner rejected claims 39, 43 and 44 under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5, 053, 050), Thomas and Boden as applied to claims 36-38 and 40-42 above, and further in view of Wevers (U.S. 4,246,660) and Dunn et al., (1995, L. Biomed. Mater. Res. 29:1363).

Claim Objections

The Examiner objected to the claim numbering. The above listing of the entire claims now pending has mooted this ground for objection and the claim numbering is now proper as to form.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 40 and 41 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter of the invention. In the Examiner's assessment, it was unclear whether the phrase "designed as" used in both claims were statements of use or statements of structural limitation.

To the extent that intended use predicates structural limitation, Applicants have amended claims 40 and 41 to use the phrase "sized and configured" in order to particularly and distinctly recite structural limitations predicated upon the intended use of the invention – namely for the partial replacement of a joint surface.

Applicants believe that the prosecution-tested phrase "sized and configured" have obviated any alleged vagueness associated with "designed as" and that this ground for rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 36, 37, 40 and 41 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Itay (U.S. 5,053,050), in light of Thomas (1997, Taber's Cyclopedic Medical Dictionary, 18th Ed.), and Boden (1999, Clin. Orthop. 376:S84-S94). According to the Examiner, U.S. 5,053,050 teaches biological joint constructs produced in vitro, comprising a biocompatible carrier material and chondrocytes, which are implantable into defective bones. Applicants disagree and respectfully traverse as follows.

A claim is anticipated under 35 U.S.C. §102(b) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim.

See Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). Moreover, elements must be arranged as required by the claim. *See In re Bond*, 910 F.2d 831(Fed. Cir. 1990).

As stated in the instant specification, (page 1, lines 22-27) "U.S. 5,053,050 describes compositions for the repair of cartilage or bone, cartilage or bone cells being incorporated into a biological, resorbable carrier substance which contains serum, fibrinogen and thrombin." In particular, U.S. 5,053,050, describes the immobilization of chondrocytes or osteoblasts (column 3, lines 35 – 45) on a viscoelastic biodegradable matrix (column 4, lines 43-44), comprising serum, fibrinogen, thrombin, calcium chloride and aprotonin (column 2, lines 38-42).

On first and elementary principles, Applicants differ vigorously with the Examiner's characterization of U.S. 5,053,050 as teaching a joint construct. As clearly stated in the specification of U.S. 5,053,050, it teaches a composition for the repair of cartilage or bone, said composition comprising chondrocytes or osteoblasts immobilized on biocompatible viscoelastic media. Although the viscoelastic composition of U.S. 5,053,050 may be poured into any geometric configuration in order to affect a repair of damaged tissue (column 4, lines 65-67), the term "joint construct" connotes a definite structural articulation which cannot reasonably be associated with the U.S. 5,053,050 patent. In fact, whereas U.S. 5,053,050 refers to compositions, the instant specification encompasses an apparatus that is fashionable, partly in vitro, for reconstructing joints.

Applicants ask the Examiner to keep a clear distinction between structure and functionality. The rejected claims 36, 37, 40 and 41, are apparatus claims, said apparati being structurally distinct from the compositional invention of U.S. 5,053,050. For the purposes of patentability, it is immaterial whether the functions of the apparatus of the present invention and the composition of U.S. 5,053,050, are related. As made explicitly clear in the instant

specification, the term *in vitro* "does not involve a joint construct grown naturally in the human or animal body" (page 3, lines 1-3). Instead, the joint construct of the present invention is produced partly in vitro.

Saying that, Applicants ask the Examiner to keep in mind that a biological "joint" comprises an osseous end and a cartilaginous end existing side by side. Unlike U.S. 5,053,050 or any other art for that matter, the instant invention is directed to and encompasses the in vitro lateral sequestration of chondrocytes and/or chondroblasts on one side and osteoblasts and or osteocytes on the other side, prior to implantation in a damaged joint in order to affect a repair of both cartilage and bone. Said lateral sequestration is attained by immobilizing each type of cell in conjunction with the appropriate tissue substance on an appropriate biocompatible media (not necessary the same on both sides), such that the osseous and the cartilagineous sides are firmly connected.

The in vitro lateral sequestration of both types of cells and their appropriate tissue substances is not taught by the alleged prior art. Although the composition of U.S. 5,053,050 may use chondrocytes or osteoblasts, in vitro, either group of cells must be used disjunctively. See for example column 3, line 42 referring to a "population expressing a chondrogenic or osteogenic phenotype." This is so because U.S. 5,053,050 teaches the repair of either cartilage or bone and starts off with a composition of either chondrogenic cells or osteogenic cells in vitro but not both. In fact, it teaches in Example 1, column 4, lines 9-12, that starting off with chondrocytes, "[A]t 2 to 6 months all the implant below the osteochondral junction is transformed into bone while articular cartilage retains its cartilaginous properties." This at least amounts to a teaching that it is not necessary to start off with a joint construct having a lateral sequestration of chondrogenic or osteogenic cells, since chondrocytes below the osteochondral

junction will be transformed to bone cells. For at least the fact that U.S. 5,053,050 does not teach the in vitro lateral sequestration of osteogenic and chondrogenic cells, there is no basis for the rejection under 35 U.S.C. § 102(b). Applicants respectfully ask that this ground for rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 38 and 42 stand rejected under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5,053,050), Thomas and Boden as applied to claims 36, 37, 40 and 41 above, and further in view of Johnson et al., (U.S. 4,156,296). According to the Examiner, Johnson et al. teaches a joint construct that in anchored into the bone shaft with a cylindrical peg. As motivation for combining Johnson et al. and U.S. 5,053,050, the Examiner argues that a skilled artisan would appreciate that a peg articulated into a bone shaft would produce a more secure fit than would two flat ends touching. Regarding the reasonableness of the expectation of success in combining Johnson et al. and U.S. 5,053,050, the Examiner asserts that U.S. 5,053,050 can be constructed in any shape or size (column 5, lines 3 -6). Applicants disagree and respectfully traverse as follows.

Applicants reiterate the arguments made in traversing the 35 U.S.C. § 102(b) above and particularly contend that a proper 103(a) rejection cannot be anchored on U.S. 5,053,050 based on the fact that the teachings of U.S. 5,053,050 differ fundamentally from the inventions of the present application as claimed and the deficiencies are not curable by the Examiner's combination.

In particular, U.S. 5,053,050 does not teach an in vitro lateral sequestration of chondrogenic and osteogenic cells prior to implantation to repair a damaged joint. Applicants

contend that the endoprosthetic device made from non-biological materials as taught by Johnson et al. cannot be combined with U.S. 5,053,050 to arrive at the present invention comprising entirely biocompatible material.

Even if the Examiner insists on making the combination, aided perhaps, by the impermissible use of hand sight, it is contended that U.S. 5,053,050 teaches the in vitro use of either osteogenic cells or chondrogenic cells but not both immobilized on biocompatible viscoelastic material and indeed teaches away from the simultaneous use of osteogenic and chondrogenic cells laterally sequestered in vitro and firmly connected to one another.

For at least the fact that the alleged combination does not teach the lateral sequestration of chondrogenic and osteogenic cells in vitro prior to articulation into damaged joints, there is no basis for the rejections under 35 U.S.C. § 103 (a). Applicants respectfully ask that these rejections be withdrawn.

Claims 39, 43 and 44 stand rejected under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5, 053, 050), Thomas and Boden as applied to claims 36-38 and 40-42 above, and further in view of Wevers (U.S. 4,246,660) and Dunn et al., (1995, L. Biomed. Mater. Res. 29:1363). According to the Examiner neither 5,053,050 nor Johnson et al. teaches joint constructs or replacements with ligaments or joint capsules, said deficiencies being cured by Weavers et al and Dunn et al. Applicants respectively disagree and traverse as follows.

Applicants reiterate the arguments made in traversing the 35 U.S.C. § 102(b) above and particularly contend that a proper 103(a) rejection cannot be anchored on U.S. 5,053,050 based on the fact that the teachings of U.S. 5,053,050 differ fundamentally from the inventions of the

present application as claimed and the deficiencies are not curable by the Examiner's combination.

In particular, U.S. 5,053,050 does not teach an in vitro lateral sequestration of chondrogenic and osteogenic cells prior to implantation to repair a damaged joint. Applicants contend that the prosthetic ligament device of Weavers comprising a plurality of interwoven parallel cord wrap elements cannot be combined with U.S. 5,053,050 to arrive at the present invention comprising entirely biocompatible materials.

Even if the Examiner insists on making the combination, aided perhaps, by the impermissible use of hand sight, it is contended that U.S. 5,053,050 teaches the in vitro use of either osteogenic cells or chondrogenic cells but not both immobilized on biocompatible viscoelastic material and indeed teaches away from the simultaneous use of osteogenic and chondrogenic cells laterally sequestered in vitro and firmly connected to one another.

For at least the fact that the alleged combination does not teach the lateral sequestration of chondrogenic and osteogenic cells in vitro prior to articulation into damaged joints, there is no basis for the rejections under 35 U.S.C. § 103 (a). Applicants respectfully ask that these rejections be withdrawn.

CONCLUSION

All of the stated grounds for rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn and the claims allowed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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